CLAIMS

We claim:

1. A stable modified antibody formulation comprising:

a modified antibody in an aqueous solution, the modified antibody comprising an antibody fragment and at least one nonproteinaceous polymer covalently attached to the antibody fragment through a linker comprising a succinimide moiety; and

a buffer that maintains the aqueous solution pH at about 3.5 to 6.

2. The formulation of claim 1, wherein the modified antibody has a specificity for human TNFα.

3. The formulation of claim 1, The method of claim 1, wherein the at least one nonproteinaceous polymer is at least one poly(ethyleneglycol) polymer.

4. The formulation of claim 3, wherein the at least one poly(ethyleneglycol) polymer is at least two methoxypoly(ethyleneglycol) polymers.

5. The formulation of claim 4, wherein the at least two methoxypoly(ethyleneglycol) polymers are covalently attached to a lysine residue linked to the succinimide moiety.

6. The formulation of claim 5, wherein the modified antibody is CDP870.

7. The formulation of claim 1, wherein the modified antibody is present at a concentration of about 50 mg/ml to about 300 mg/ml.

8. The formulation of claim 1, wherein less than about 5% of a succinimide ring of the succinimide moiety is present in hydrolyzed form.

9. The formulation of claim 1, wherein less than about 5% of the modified antibody is present in an aggregated form.

10. The formulation of claim 1, wherein the buffer is an acetate buffer.

11. The formulation of claim 1, wherein the formulation is isotonic.

12. The formulation of claim 10, wherein the formulation further comprises a tonicifying amount of sodium chloride.

13. A stable CDP870 formulation, comprising CDP870 in an aqueous solution and a buffer that maintains the pH of the solution from about 3.5 to about 6.0.

14. The formulation of claim 13, wherein the formulation is isotonic.

15. The formulation of claim 14, wherein the formulation further comprises a tonicifying amount of a salt.

16. The formulation of claim 15, wherein the salt is sodium chloride.

17. The formulation of claim 13, wherein the modified antibody is present at a concentration of about 50 mg/ml to about 300 mg/ml.

18. A method of treatment or prophylaxis of a disease, comprising steps of:

a. providing a formulation comprising a modified antibody in an aqueous solution and a buffer that maintains the formulation pH at about 3.5 to about 6.0, the modified antibody comprising an antibody fragment and at least one nonproteinaceous polymer covalently attached to the antibody fragment through a succinimide moiety, wherein the antibody has an affinity for an inflammatory disease antigen; and

b. delivering a pharmaceutically effective dose of the formulation to a subject to treat or prevent a disease associated with a disease antigen.

19. The method of claim 18, wherein the disease antigen is TNFα.

20. The method of claim 19, wherein the disease is rheumatoid arthritis.

21. The method of claim 18, wherein the buffer is acetate buffer.

22. The method of claim 18, wherein the at least one nonproteinaceous polymer is at least one poly(ethyleneglycol) residue.

23. The method of claim 22, wherein the at least one poly(ethyleneglycol) residue is at least one methoxypoly(ethyleneglycol) residue.

24. The method of claim 23, wherein the modified antibody is CDP870.

25. The method of claim 18, wherein the modified antibody is present in the formulation at a concentration of about 50 mg/ml to about 300 mg/ml.

26. The method of claim 18, wherein the dose of the formulation is delivered to the subject parenterally.

27. The method of claim 18, wherein the subject is a mammal.

28. The method of claim 27, wherein the subject is a human being.